Rapid Test Evaluations

- Los Angeles County:
  - Lab evaluation on 400 stored samples to select RTs for further evaluation
  - Clinical study, 900 persons with known HIV status, to establish performance using whole blood, finger-stick specimens
  - Clinical study, 6,000 persons with unknown HIV status to determine sensitivity, specificity, and predictive value of combinations of RTs.

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Rapid Test Performance: Serum

	Sensitivity	Specificity
Determine	100%	98%
Hemastrip	98.5%	99.5%
Quix	100%	97.5%
Unigold	99.0%	96.0%
SUDS	97.9%	94.5%
HIV 1-2 EIA	-	95.1%

(196 HIV+, 200 HIV- stored sera)

Preliminary data. Not for citation or distribution

CDC

FDA Considerations

- Investigational Device Exemption (IDE)
- Expanded Access Treatment IDE ?

Rapid Test Performance: Finger Stick

	False Negative	Sensitivity	False Positive	Specificity
Determine	0	100%	2	99.6%
Hemastrip	13	96.2%	1	99.8%
Quix	13	96.2%	5	98.9%
Unigold	28	91.8%	0	100%

(Prospective, 341 HIV+, 466 HIV-)

Preliminary data. Not for citation or distribution

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Rapid Test Performance: Whole Blood

	False Negative	Sensitivity	False Positive	Specificity
Determine	0	100%	0	100%
Hemastrip	8	97.7%	0	100%
Quix	2	99.4%	5	98.9%
Unigold	16	95.3%	1	99.8%
SUDS (plasma)	4	98.8%	2	99.3%

341 HIV+, 466 HIV- venipuncture specimens

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Adjusted Rapid Test Performance: Discordants Retested on Plasma

	Retest results			
	Pos/tested False Negatives	Neg/tested False Positives	Adjusted Sensitivity	Adjusted Specificity
Determine	0	0	100%	100%
Hemastrip	3 / 8	0	98.5%	100%
Quix	1 / 2	1 / 5	99.7%	99.1%
Unigold	13 / 16	0 / 1	99.1%	99.8%
SUDS	3 / 4	1 / 2	99.7%	99.8%

341 HIV+, 466 HIV- persons

Preliminary data. Not for citation or distribution

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